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According to the Request, the "examiner is requiring the Applicant to state on the record what nerves the applicant considers the intercostal nerve branches to consist of. ... This information is required to extend the domain of search for prior art." (Request, p. 2). In response, Applicant states on the record that the nerves Applicant considers to be intercostal nerve branches are those nerves that are so defined in the originally filed specification and those nerves that are so identified in the ordinary and customary terminology of the art at the time of the invention.

This Request is apparently made because the claims recite, for example, "implanting the stimulator adjacent to at least one tissue influencing the angina pectoris of the patient, which tissue is at least one of an intercostal nerve and an intercostal nerve branch." It is unclear, however, why a further statement regarding the meaning of "intercostal nerve branch" is needed by the Examiner.

Applicant notes that there are well-established legal rules for ascertaining the definition of a term used in a patent claim. During examination, the USPTO gives claims their broadest reasonable interpretation. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear contrary definition in the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (discussed below); *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004).

"[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, ___ F.3d ___, 75

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USPQ2d 1321 (Fed. Cir. 2005) (*en banc*). *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003) ("In the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art."). See MPEP § 2111.01.

Consequently, Examiner *must* rely on any definition of the term "intercostal nerve branches" as provided in Applicant's specification and, to the extent not inconsistent with that definition, the ordinary and customary meaning in the art at the time of the invention. For the Applicant to provide any other definition at this point in the examination process would be, in essence, the introduction of new matter into the application to the extent that such definition would be used to supplement or supersede the specification in construing the relevant claim terms. As the Examiner is perfectly well aware, the Applicant cannot introduce new matter into the application. MPEP § 2163.06. Moreover, the Applicant cannot add to or change what the specification itself says or doesn't say by making subsequent statements during prosecution.

Thus, in response to the Request, Applicant states that the nerves Applicant considers to be intercostal nerve branches are those nerves that are so defined in the originally filed specification and those nerves that are so identified in the ordinary and customary terminology of the art at the time of the invention.

In making the Request, the Examiner cites 37 C.F.R. § 1.105. This rule allows the Examiner to request "such information as may be reasonably necessary to properly examine or

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treat" an application. (37 C.F.R. § 1.105). In contrast, however, the Request made here does not appear reasonably necessary to properly examine or treat the application.

The Examiner has asked that Applicant further define a specific claim term. As demonstrated above, the Office is to give each claim term its plain and ordinary meaning in the relevant art unless the specification clearly provides an alternate definition. With this rule in place, there is no purpose served by asking Applicant to give some further definition for a claim term. Consequently, the Request made here is not "reasonably necessary to properly examine or treat" the application. The application can be properly examined using the normal and established procedures of the U.S. Patent Office.

Applicant further notes that 37 C.F.R. § 1.105 gives a number of examples of what information may be properly sought in a Request for Information. None of these examples include requiring the Applicant to give a supplemental definition to a claim term.

Additionally, the Examiner has stated that the information requested is "required to extend the domain of search for prior art." (Request, p. 2). However, defining the scope of a prior art search is also *not* listed in Rule 105 as an appropriate reason for requesting information from the Applicant. Moreover, it is not the place of the Applicant, but rather considered within the professional range of the Examiner, to set the scope and domain of the Office's prior art search.

According to the Request, a "broader range of art to search is necessary to establish the level of knowledge of those of ordinary skill in the claimed subject matter." The Examiner, however, should be able to conduct a prior art search that establishes the level of knowledge of

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those of ordinary skill in the art without requiring the Applicant to provide new definitions for claim terms.

The Request also states that the requested information is needed "to complete the background description in the disclosure by documenting the nerves which applicants consider to be the intercostal nerve branches." In response, Applicant considers the background description in the disclosure to be complete as originally filed.

The Request further states that the requested information is needed "to identify products and services embodying the disclosed subject matter of intercostal nerve branches and identify the properties of similar products and services found in the prior art." In response, Applicant believes that the Examiner should, per standard procedure, look for prior art that is read on by Applicant's claims, if any such exists. No additional information is needed to conduct such an examination of the application.

For at least these reasons, the outstanding Request does not appear to be a proper application of 37 C.F.R. § 105. For at least these reasons, the Request should be withdrawn and the examination of the application resumed promptly so as to avoid any further waste of time or unnecessary loss of patent term for the Applicant.

The Request requests "a list of keywords that are particularly helpful in locating publications related to the disclosed art of stimulating intercostal nerves and intercostal nerve branches." (Request, p. 3). While Applicant is somewhat surprised at this request on the part of the Examiner, the obvious answer is: "stimulation" and "intercostal nerve" alone or in combination with "branch."

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Applicant notes that typically, when the Examiner is unable to find relevant prior art, that indicates that the subject matter of the application is patentable, rather than that a request should be made of the Applicant for some re-definition of the claim terms.

Lastly, the Request asks that Applicant provide copies of each publication which any of the applicants authored or co-authored and which describe the disclosed subject matter. (Request, p. 3). This amounts to nothing more than a request that Applicant fulfill the Duty of Disclosure under 37 C.F.R. § 1.98. Applicant has already complied with this rule and has nothing further to add at this time.

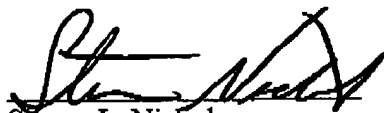
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In conclusion, Applicant has provided herein a definition of intercostal nerve branches that is consistent with the originally-filed specification, the plain and ordinary meaning of the term in the art and applicable USPTO practice. Nothing more can be reasonably required without asking the Applicant to introduce new matter into the application.

Respectfully submitted,

DATE: November 17, 2006



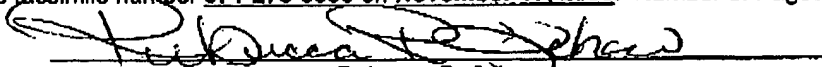
Steven L. Nichols

Registration No. 40,326

Steven L. Nichols, Esq.
Managing Partner, Utah Office
Rader Fishman & Grauer PLLC
River Park Corporate Center One
10653 S. River Front Parkway, Suite 150
South Jordan, Utah 84095
(801) 572-8066
(801) 572-7666 (fax)

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Rebecca R. Schow